REMARKS/ARGUMENTS

Status of the Claims

Claim 43 has been amended for consistency. Claims 43 and 48 have been amended to recite that the presently-claimed methods include continuously or repeatedly administering an opioid narcotic analgesic and a tolerance-reducing or dependence-reducing amount of a nontoxic VR1 antagonist. Support for the amendments can be found throughout the present specification, for example, see page 23, lines 12-16 and 27-31 of the application as filed.

Claims 64-71 are new. Support for the new claims can be found in the specification and claims as filed, e.g., page 26, lines 7-10. No new matter has been added.

In the Office Action, claims 1-6, 25-42 and 53-57 and 59 were indicated to be withdrawn, and claims 43-52 and 60-63 to be presently under examination. In addition, new claims 64-71 are under examination.

Applicants note with appreciation the Examiner's withdrawal of the previous rejections under 35 U.S.C. §112, first paragraph. Reconsideration of the remaining grounds of rejection is requested.

Rejection of claims under 35 USC 102(e)

In the Office Action, claims 43-45 and 48-50 again stand rejected under 35 U.S.C. §102(e), as allegedly anticipated by Kyle et al., U.S. Patent No. 6,974,818 (the "Kyle patent"). This rejection is traversed.

(1) The Kyle Patent is not an effective reference for purposes of 35 USC 102(e)

Without agreeing that the disclosure of the Kyle patent would anticipate or render obvious any of the claims of the instant application, Applicants contend that the Kyle patent is not an effective reference against the claims presently under examination.

In the Interview of July 1, 2008 (summarized in the Pre-Appeal Brief Request for Review discussed previously), the Examiners indicated that they consider the Kyle

patent (U.S. Patent No. 6,974,818) to form the basis for a rejection under 35 USC 102(e), and that the disclosure of the Kyle patent (rather than the disclosure of the Kyle priority application(s)) is relevant for the purposes of 35 USC 102(e). Applicants cannot agree. As discussed in the previous responses (filed August 10, 2007, and April 8, 2008), the disclosure of the Kyle patent is not available for citation under 102(e) unless such disclosure also appears in one of the Kyle patent's priority provisional applications.

MPEP 706.02 (f)(1) I (B) states in part: "The 35 U.S.C. 102(e) date of a reference that did not result from, nor claimed the benefit of, an international application is its earliest effective U.S. filing date, taking into consideration any proper benefit claims to prior U.S. applications under 35 U.S.C. 119(e) or 120 **if** the prior application(s) properly supports the subject matter used to make the rejection in compliance with 35 U.S.C. 112, first paragraph" (emphasis added). MPEP 2136.03(III) reiterates this requirement.

Therefore, an issued patent can be applied as a reference under 35 U.S.C. 102(e) only if the utility application, or one or more of the priority applications, was filed before the invention of the present claims by the present Applicants.

Applicants contend that the present claims are entitled to at least the filing date of the priority application USSN 60/433,363, filed December 13, 2002, to which the present application claims priority. The Kyle utility application (USSN 10/374,863) was filed on February 27, 2003, and thus was not filed "before the invention by the [present] applicant for patent".[1] Therefore, the disclosure of the Kyle utility application (USSN 10/374,863) and the Kyle patent as issued cannot be used in a rejection under 35 U.S.C. 102(e) unless such disclosure is present in an application to which the Kyle utility application properly claims priority. Cf. Ex parte Yamaguchi, 88 USPQ2d 1606 (Bd. Pat. App. & Int. 2008).

It follows that the discussion in the Office Action of the disclosure of the Kyle patent (see, e.g., the Office Action at page 3, last paragraph) is irrelevant and improper as the basis for a rejection under 35 U.S.C. 102(e) unless that disclosure is found in

[1] Solely for purposes of this discussion, the filing date of the priority application USSN 60/433,363 is mentioned as the latest date of invention of the present claims. Applicants reserve the right to assert an earlier date of invention.

one of the Kyle priority applications. The rejection of the present claims based on the asserted portions of the Kyle patent cannot stand.

(2) The Kyle Priority application(s) do not anticipate the pending claims[2]

The MPEP states that, in order to anticipate a claimed invention, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." MPEP 2131 (emphasis supplied, citation omitted).

Furthermore, the Court of Appeals for the Federal Circuit has stated that "In order to anticipate a claimed invention, a prior art reference must enable one of ordinary skill in the art to make the invention without undue experimentation . . . In other words, the prior art must enable the claimed invention." Impax Laboratories, Inc. v. Aventis Pharmaceuticals, Inc., 545 F3d 1312, 88 USPQ2d 1381, 1383 (Fed. Cir. 2008) (citations omitted).

The Examiner asserts that in the Kyle patent's priority application 60/411,084 it is "taught that the compounds [of the Kyle priority application 60/411,084] treat addictive disorders." The disclosure in that priority application regarding addictive disorders is limited to the lines cited by the Examiner (page 20, lines 14-23) (and similar language at page 21, lines 7-11), which merely recite that compounds disclosed therein "are useful for treating or preventing ... an addictive disorder."

As previously mentioned (see the previous response April 8, 2008), the bare recitation of "an addictive disorder" in the Kyle priority application can hardly be said to describe or enable methods for inhibiting the development of tolerance to or dependence on a narcotic analgesic, as recited in the pending claims under examination.

Notably, in Kyle's 60/411,084 priority application, there is not the slightest enablement provided for using any compound "for treating or preventing ... an addictive disorder" nor is there any disclosure at all (the ultimate in non-enablement) of most of

[2] The Kyle utility application claims priority to two provisional applications. The Office Action does not allege that Kyle priority application 60/360,172 anticipates the present claims, and Applicants contend that it does not, so it will not be further discussed.

the critical added citations from the Kyle patent 6,974,818 used in the Office Action in making the pending 102(e) rejections.

Moreover, Applicants point out that the bare recitation of "an addictive disorder" in the Kyle priority application can hardly be said to describe or enable methods for inhibiting the development of tolerance to or dependence on a narcotic analgesic, as recited in the pending claims under examination.

To the extent that the Kyle priority application does mention "that the compounds of the [Kyle] invention are used for the treatment of addictive disorders," as stated in the Office Action, Applicants submit that the Kyle priority application does not enable such use.

Of the disclosures in the Kyle patent 6,974,818 cited by the Examiner, only the first (which merely discloses that Kyle's thiadiazolylpiperazine compounds can be used to inhibit VR1 function) is arguably supported by the disclosure of Kyle's 60/411,084 priority application. As mentioned above, the disclosure in the Kyle patent (at column 31, line 18) that "[t]hiadiazolepiperazine Compounds can be used to treat or prevent an addictive disorder" does not find enabling support in the Kyle priority application; certainly, the language of the Kyle patent relating to "an opioid-related [addictive] disorder" (column 31, lines 24-25) is not found in the Kyle priority application. Thus, these other cited disclosures of the Kyle patent (6,974,818) are simply not available to be used to reject the present claims pursuant to 35 U.S.C. §102(e), and the pending §102(e) rejection is completely untenable without them.

Even further, Applicants note that the now-pending claims recite that the presently-claimed methods include continuously or repeatedly administering an opioid narcotic analgesic and a tolerance-reducing or dependence-reducing amount of a nontoxic VR1 antagonist. The Kyle priority application 60/411,084 does not teach or suggest continuous or repeated administration of both an opioid narcotic analgesic and a tolerance-reducing or dependence-reducing amount of a nontoxic VR1 antagonist.

Reconsideration and withdrawal of the rejection is proper and the same is requested.

Rejection of claims under 35 U.S.C. §103(a)

In the Office Action (at pages 7-8), claims 46-47, 51-52, and 62-63 stand rejected under 35 U.S.C. §103(a), as allegedly unpatentable over Kyle et al., U.S. Patent No. 6,974,818, in view of Bakthavatchalam et al., U.S. Patent No. 6,723,730 (the "Bakthavatchalam patent"). This rejection is traversed.

As noted above, the Kyle patent simply does not teach (for purposes of 35 U.S.C. 102(e)) what the Office Action asserts that it teaches. As also discussed above, the Kyle priority application(s) do not teach or suggest methods for inhibiting the development of tolerance to or dependence on a narcotic analgesic, as recited in the pending claims. Moreover, the Kyle patent does not teach or suggest continuous or repeated administration of both an opioid narcotic analgesic and a tolerance-reducing or dependence-reducing amount of a nontoxic VR1 antagonist.

The Office Action does not contend that the Bakthavatchalam patent can supply these omitted teachings. The Bakthavatchalam patent does not teach or suggest continuous or repeated administration of both an opioid narcotic analgesic and a tolerance-reducing or dependence-reducing amount of a nontoxic VR1 antagonist. Applicants contend the rejection over the Kyle patent in view of the Bakthavatchalam patent is therefore improper and should be withdrawn.

Reconsideration and withdrawal of the rejection is proper and the same is requested.

CONCLUSION

For at least the foregoing reasons, Applicants contend that the rejections of record should be withdrawn, and that the present application is in condition for allowance. Early and favorable consideration of the application is earnestly solicited.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper

hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 60004 (72021).

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Respectfully submitted,

By: /Mark D. Russett/
Mark D. Russett, Registration No.: 41,281
EDWARDS ANGELL PALMER & DODGE LLP
P.O. Box 55874
Boston, Massachusetts 02205
(617) 239-0100
Attorneys/Agents For Applicants